

## REMARKS

This amendment corrects the typographical error noted by the examiner.

No new matter is presented and the substituted term is inherent in the rest of the claim so the amendment does not entail issues of patentability.

The rejection of claims 1, 2, 6, 14-18 and 48-51 over the prior art is respectfully traversed.

The Shell reference (WO 97/47285) does indeed disclose the use of a solid drug matrix that is large enough to be retained in the stomach during the fed mode, but there is nothing in the Shell reference (WO 97/47285) to suggest the use of a fed-mode inducing agent, much less one in the same matrix as a drug. While the Acharya reference (US Patent No. 5,686,094) lists docusate as a medicinal agent in a controlled release formulation and the Sewester et al. reference ("Facts and Comparisons") lists docusate as a laxative (specifically, a fecal softener), neither of these two references suggest the desirability of retaining docusate or any other laxative in the stomach. In fact, fecal softeners would serve no purpose in the stomach, only in the large intestine. Thus, there is no reason suggested by the prior art to use a fecal softener in a drug matrix that is large enough to be retained in the stomach. As a result, this combination of references does not add up to a suggestion of a pharmaceutical composition that contains both docusate (or any other laxative) and a drug that is retained in a matrix large enough to be retained in the stomach.

Laxatives are not known to affect the motility functions of the gastrointestinal tract, particularly its stomach emptying behavior nor are they known to induce transitions between the fed mode and the fasting mode. Laxatives and agents that control stomach emptying act on different sites and receptors in the GI tract. If there are any laxatives that act on the same sites as fed mode inducing agents (which has not been established), the effect would be the opposite, since the typical laxative would seek to empty the stomach contents rather than retain them. Thus, a disclosure that a particular

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MARKEY et al.

PATENT

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agent is a laxative would tend to direct one away from its use as a fed mode inducing agent, and there would be no reason to combine a laxative with a drug.

For this reason, the combination of Shell, Acharya and Sewester et al. do not suggest the present invention as expressed in any of the claims under examination, and reconsideration is respectfully requested.

Should any matters remain that can be resolved by a telephone conference, the examiner is encouraged to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

2. (amended) A pharmaceutical composition in accordance with claim 1 in which said fed mode inducing agent is retained in said solid matrix with said drug, said solid matrix causing release of both said fed mode **inducing** [reducing] agent and said drug in a sustained manner.